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EXAMINER

RAPILLO, KRISTINE K

ART UNIT

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3626

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/813,968	<b>Applicant(s)</b> UNDERWOOD ET AL.	
	<b>Examiner</b> KRISTINE K. RAPILLO	<b>Art Unit</b> 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Claims 1 – 20 are pending.

#### ***Notice to Applicant***

1. This communication is in response to the amendment submitted May 15, 2008. No claims were amended. Claims 1 - 20 are rejected.

#### ***Drawings***

2. The objection to the drawings are hereby withdrawn based upon the amendment submitted May 15, 2008.

#### ***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1 – 18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In order for a method to be considered a "process" under 35 USC § 101, a claimed process must either: (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials). *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972). If neither of these requirements is met by the claim, the method is not a patent eligible process under 35 USC § 101 and is non-statutory subject matter. With regard to claim 1, the method claimed by the Applicant is not tied to another statutory class as it recites the limitations "determining a first score...", "determining a second score....", "comparing the first score.....", "providing...result of comparison", and "intervening ....based on result of comparison". The method claimed does not include a particular machine, nor does it transform the data identifying the patient. The method steps recited in the body of claim 1 could reasonably be interpreted to encompass a human being performing these steps.

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In regard to claim 16, the citation “wherein the step of providing health care providers with access to the health care history is carried out by an internet server that provides information that may be displayed on an internet browser” includes only a nominal recitation of an apparatus. Nominal recitations of structure in an otherwise ineligible method fail to make the method a statutory process. Claims 1 – 15 and 17 - 18 have similar deficiencies as noted above with regard to claims 1 and 16; therefore claims 1 – 15 and 17 – 18 are rejected for substantially the same reason.

**NOTE:** The following art rejections assume that the subject matter of claims 1 – 18 will be amended to recite statutory subject matter. The art rejections are provided herein below for the Applicant’s consideration on the condition that the Applicant properly incorporates concrete and tangible elements as discussed above in the rejections under 35 U.S.C. 101 in the next communication sent in response to the present Office Action.

#### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3 – 7, 13 – 14, and 16 – 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trusheim et al. (U.S. Patent No. 6,385,589 B1) in view of Minturn (U.S. Patent No. 5,692,501) in further view of Goetzke et al. (U.S. Publication No. 2002/012866A1).

In regard to claim 1, Trusheim et al. teaches a method for administering reductions in health care costs for those participants in a health insurance plan for whom future health care costs may be reduced through intervention (“intervention candidates”) comprising: determining a first score for an intervention candidate (column 10, lines 30 – 34); determining a second score for the intervention candidate, which second score depends on the intervention candidate’s prior consumption of a plurality of predetermined

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health care services (column 10, lines 24 – 26); and, providing to select individuals access to the health care history of the intervention candidate and the result of the comparison (column 10, lines 35 - 39).

Trusheim et al. fails to teach a method where the first score reflects the predicted utilization of future health care services; comparing the first score against a first threshold value and the second score against a second threshold value and generating a result of such comparison; and, intervening in the health care regimen of the intervention candidate depending on the result of the comparison.

Minturn teaches a method where the first score reflects the predicted utilization of future health care services (column 12, lines 33 – 35) and comparing the first score against a first threshold value and the second score against a second threshold value and generating a result of such comparison; and, intervening in the health care regimen of the intervention candidate depending on the result of the comparison (abstract and column 12, lines 48 – 61) where the first score (

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a method where the first score reflects the predicted utilization of future health care services and comparing the first score against a first threshold value and the second score against a second threshold value and generating a result of such comparison and intervening in the health care regimen of the intervention candidate depending on the result of the comparison as taught by Minturn with the motivation of teaching patients the importance of positive health decisions (column 11, lines 17 – 36).

In regard to claim 2, Trusheim et al. teaches a method for administering reductions in health care costs as per claim 1.

Trusheim et al. fails to teach wherein the second score is determined by adding a plurality of values, each of which represents the intervention candidate's consumption of a different health care service.

Goetzke et al. teaches a method wherein the second score is determined by adding a plurality of values, each of which represents the intervention candidate's consumption of a different health care

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service. Goetzke et al. discloses a method where letter designations are used to determine the various pain types, etiology, and pain sites of a patient (paragraphs [0058], [0059], and [0060]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a method wherein the second score is determined by adding a plurality of values, each of which represents the intervention candidate's consumption of a different health care service as taught by Goetzke et al. with the motivation of providing an efficient and effective health care team while at the same time reducing costs (paragraph [0027]).

In regard to claim 3, Trusheim et al. teaches a method, as per claim 2, wherein one of the pluralities of values represents the amount of medical claims allowed (column 21, lines 39 – 47). Trusheim et al. discloses a method in which a health care provider can access claims via a web browser thus indicating all claims within a specified date ranges (Figure 30).

In regard to claim 4, Trusheim et al. teaches a method as per claim 2.

Trusheim et al. fails to teach a method wherein one of the plurality of values is selected from the group consisting of: a value representing the number of medical specialists that treated the candidate, a value representing the number of inpatient admissions, a value representing the number of chronic diseases for which the candidate was treated, a value representing the number of prescriptions for unique drugs, or a value representing the number of emergency room visits without admission in a hospital.

Goetzke et al. teaches a method wherein one of the plurality of values is selected from the group consisting of: a value representing the number of medical specialists that treated the candidate, a value representing the number of inpatient admissions, a value representing the number of chronic diseases for which the candidate was treated, a value representing the number of prescriptions for unique drugs, or a value representing the number of emergency room visits without admission in a hospital (paragraph [0030]).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method wherein one of the plurality of values is selected from the group

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consisting of: a value representing the number of medical specialists that treated the candidate, a value representing the number of inpatient admissions, a value representing the number of chronic diseases for which the candidate was treated, a value representing the number of prescriptions for unique drugs, or a value representing the number of emergency room visits without admission in a hospital as taught by Goetzke et al. with the motivation of ensuring a patient receives quality health care in a cost efficient manner (paragraph [0028]).

In regard to claim 5, Trusheim et al. teaches a method as per claim 1 for administering reductions in health care costs.

Trusheim et al. fails to teach a method wherein the plurality of predetermined health care services includes one health care service selected from the group consisting of: treatment by a medical specialists, inpatient admissions, treatment for a chronic disease, prescriptions for unique drugs, and emergency room visits without admission in a hospital.

Goetzke et al. teaches a method wherein the plurality of predetermined health care services includes one health care service selected from the group consisting of: treatment by a medical specialists, inpatient admissions, treatment for chronic diseases, prescriptions for unique drugs, and emergency room visits without admission in a hospital (paragraphs [0029] and [0030]). Goetzke et al. discloses the practice of general practitioners referring patients to medical specialists.

The motivation for combining the teachings of Trusheim et al. and Goetzke et al. is discussed in the rejection of claim 4, and incorporated herein.

In regard to claim 6, Trusheim et al. teaches a method, as per claim 1, for administering reductions in health care costs.

Trusheim et al. fails to teach a method wherein the step of generating a result includes generating a first result that indicates whether the first score exceeds the first threshold value, a second result that indicates whether the second score exceeds the second threshold value, and a composite result that represents both the first and second results.

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Goetzke et al. teaches a method wherein the step of generating a result includes generating a first result that indicates whether the first score exceeds the first threshold value, a second result that indicates whether the second score exceeds the second threshold value, and a composite result that represents both the first and second results (paragraphs [0061] and [0079]). Goetzke et al. discloses a method in which outside data (i.e. threshold) is compared to the data of the patient of interest.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a method wherein the step of generating a result includes generating a first result that indicates whether the first score exceeds the first threshold value, a second result that indicates whether the second score exceeds the second threshold value, and a composite result that represents both the first and second results as taught by Goetzke et al. with the motivation of providing a health plan that is beneficial to both the patient and the payer (i.e. insurer) – paragraph [0076].

In regard to claim 7, Trusheim et al. teaches a method, as per claim 1, for administering reductions in health care costs.

Trusheim et al. fails to teach a method wherein the step of intervening in the health care regimen of a candidate occurs only if the result of comparison indicates that the first score exceeds the first threshold value and a second result that indicates whether the second score exceeds the second threshold value.

Goetzke et al. teaches a method wherein the step of intervening in the health care regimen of a candidate occurs only if the result of comparison indicates that the first score exceeds the first threshold value and a second result that indicates whether the second score exceeds the second threshold value (paragraphs [0061] and [0068]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a method wherein the step of intervening in the health care regimen of a candidate occurs only if the result of comparison indicates that the first score exceeds the first threshold value and a second result that indicates whether the second score exceeds the second threshold value as taught by



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Goetzke et al. with the motivation of providing an individualized health care plan based on the scores of a patients medical profile (paragraph [0067]).

In regard to claim 8, Trushiem et al. and Goetzke et al. teach a method, as per claim 1, in administering reductions in health care costs.

Trusheim et al. and Goetzke et al. fail to teach a method wherein the step of intervening includes causing a health care provider to contact a candidate in order to recommend a change in the candidate's health care regimen.

Minturn teaches a method wherein the step of intervening includes causing a health care provider to contact a candidate in order to recommend a change in the candidate's health care regimen (column 10, lines 47 – 58).

The motivation to combine the teachings of Trusheim and Minturn is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 9, Trusheim et al. and Goetzke et al. teach a method as per claim 8.

Trusheim et al. and Goetzke et al. fail to teach a method wherein the recommendation includes that the candidate increases physical activity and cardio respiratory fitness.

Minturn teaches a method wherein the recommendation includes that the candidate increases physical activity and cardio respiratory fitness (column 17, lines 27 – 29).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method wherein the recommendation includes that the candidate increase physical activity and cardio respiratory fitness as taught by Minturn with the motivation of improving their cardiovascular system to maintain a healthy lifestyle (column 17, line 67 through column 18, line 3).

In regard to claim 11, Trusheim et al. teaches a method as per claim 8.

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Trusheim et al. fails to teach a method wherein the recommendation includes that the candidate enters a substance abuse program.

Goetzke et al teaches a method wherein the recommendation includes that the candidate enters a substance abuse program (paragraph [0067]). Goetzke et al. discloses a system in which chronic drug use is categorized in the medical profile and can be translated into a treatment. The Examiner interprets this to imply that an indication of chronic drug use can be flagged so that the patient can be placed in a treatment program for substance abuse (paragraph [0068]).

The motivation for combining the teachings of Trusheim et al. and Goetzke et al. is discussed in the rejection of claim 4, and incorporated herein.

In regard to claim 12, Trusheim et al. teaches a method as per claim 8.

Trusheim et al. fails to teach a method wherein the recommendation includes that the candidate consults a mental health practitioner.

Goetzke et al. teaches a method wherein the recommendation includes that the candidate consults a mental health practitioner (paragraph [0067]). Goetzke et al. discloses a system in which depression (which is included under the broad category of mental health) is categorized in the medical profile and can be translated into a treatment. The Examiner interprets this to imply that an indication of mental health issues can be flagged so that the patient can be placed in a treatment program for mental health (paragraph [0068]).

The motivation for combining the teachings of Trusheim et al. and Goetzke et al. is discussed in the rejection of claim 4, and incorporated herein.

In regard to claim 13, Trusheim et al. teaches a method, as per claim 1, further including the step of generating a plurality of flags, wherein each flag has a status that represents health information of an intervention candidate (column 14, lines 42 – 47 and column 18, lines 41 – 45).

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In regard to claim 14, Trusheim et al. teaches the method of claim 13, wherein one of the plurality of flags represents the likelihood that an intervention candidate will claim disability under a disability insurance plan (column 21, lines 26 – 47). Trusheim et al. discloses a computerized system which tracks all claims as well as all insurance claims. Therefore, it is obvious that the system described will enable a user to determine the likelihood of a patient filing a disability claim.

In regard to claim 15, Trusheim et al. and Goetzke et al. teach a method, as per claim 1, in administering reductions in health care costs.

Trusheim et al. and Goetzke et al. fail to teach a method wherein the second score indicates the potential for health care cost reduction of the candidate as determined relative to other participants in the health insurance plan.

Minturn et al. teaches a method wherein the second score indicates the potential for health care cost reduction of the candidate as determined relative to other participants in the health insurance plan (column 12, lines 24 – 25 and column 30, lines 43 – 65).

Therefore it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method wherein the second score indicates the potential for health care cost reduction of the candidate as determined relative to other participants in the health insurance plan as taught by Minturn with the motivation of improving participants health by offering periodic monitoring which can thus lead to a decrease in insurance costs (column 9, lines 38 – 43).

In regard to claim 16, Trusheim et al. teaches the method of claim 1, wherein the step of providing health care providers with access to the health care history is carried out by an Internet server that provides information that may be displayed on an Internet browser (column 17, lines 14 – 22).

In regard to claim 17, Trusheim et al. teaches a method of claim 16, wherein the information that may be displayed on an Internet browser includes a plurality of flags, wherein each flag has a status that represents health information of an intervention candidate (column 18, lines 41-45 and Figure 16).

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Trusheim et al. discloses a method in which a medical event is flagged and a notification is sent to the web server.

In regard to claim 18, The method of claim 17, wherein one of the pluralities of flags represents the likelihood that an intervention candidate will claim disability under a disability insurance plan (column 21, lines 26 – 47). Trusheim et al. discloses a computerized system which tracks all claims as well as all insurance claims. Therefore, it is obvious that the system described will enable a user to determine the likelihood of a patient filing a disability claim.

In regard to claim 19, Trusheim et al. teaches a method for administering reductions in health care costs comprising: storing in at least one database health information relating to a plurality of health insurance plan participants (column 11, lines 35 – 44); generating a plurality of flags for each intervention candidate, wherein each flag has a status that represents a health condition of an intervention candidate (column 10, line 50 through column 11, line 3 and column 21, lines 17 –25) where Trusheim discloses a data repository program which generates a variety of clinical alerts which are equated to flags. A clinical alert is a notification which alerts the caregiver to any ongoing or historical medical problems, thus it is a considered a flag; storing the health information and flags for each intervention participant in an separate database (column 17, lines 23 – 36); and permitting select individuals to retrieve and display via a graphical user interface each intervention candidate's health information and flags as stored in the separate database (column 18, lines 10 – 16).

Trusheim et al. fails to teach a method identifying from stored health information candidates for whom health care costs may be reduced through intervention ("intervention candidates").

Goetz et al. teaches a method identifying from stored health information candidates for whom health care costs may be reduced through intervention ("intervention candidates") – paragraph [0026].

The motivation for combining the teachings of Trusheim et al. and Goetzke et al. is discussed in the rejection of claim 2, and incorporated herein.

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In regard to claim 20, Trusheim et al. teaches a method as per claim 19, wherein one of the plurality of flags represents the likelihood that an intervention candidate will claim disability under a disability insurance plan (column 21, lines 26 – 47). Trusheim et al. discloses a computerized system which tracks all claims as well as all insurance claims. Therefore, it is obvious that the system described will enable a user to determine the likelihood of a patient filing a disability claim.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trusheim et al., Goetzke et al., and Minturn as applied to claim 8 above, and further in view of Chao (U.S. Publication No. 2006/0178915 A1).

In regard to claim 10, Trusheim et al., Goetzke et al., and Minturn teach a method as per claim 8.

Trusheim et al., Goetzke et al., and Minturn fail to teach a method wherein the recommendation includes that the candidate switch prescriptions from a brand name drug to a generic drug.

Chao teaches a method wherein the recommendation includes that the candidate switch prescriptions from a brand name drug to a generic drug (paragraph [0089]).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method wherein the recommendation includes that the candidate switch prescriptions from a brand name drug to a generic drug as taught by Minturn with the motivation of providing accessible and affordable medication to patients through a health care plan (paragraph [0015]).

### ***Response to Arguments***

8. In regard to claim 1, the Applicant argues that Minturn does not teach a first score reflecting the predicted utilization of future health care services. The Examiner respectfully disagrees. Minturn teaches a method and system of ranking an individual or group of individuals using a numeric score based upon a patient(s) wellness, health, fitness, and risk (Minturn: Abstract, Figures 6 – 9). These scores are then used to assist employers in determining the utilization of medical services (column 12, lines 33 – 35).

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9. In response to the Applicant argument of claim 1 in which the Applicant claims Goetzke does not describe the comparison of a first score against a first threshold value and a second score against a second threshold value and generating a result based upon the comparison and claim 19, it is respectfully submitted that the Examiner has applied new passages and citations to the claims as such; the Applicant's remarks with regard to the application of the Trusheim et al, Minturn, and Goetzke et al. references are addressed in the above Office Action.

### ***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTINE K. RAPILLO whose telephone number is (571)270-3325. The examiner can normally be reached on Monday to Thursday 6:30 am to 4 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KKR

/Robert Morgan/  
Primary Examiner, Art Unit 3626